

Citation:

Ebbeling CB, Feldman HA, Osganian S, Chomitz VR, Ellenbogen SJ, Ludwig DS. Effects of decreasing sugar sweetened beverage consumption on body weight in adolescents: a randomized controlled pilot study. *Pediatrics*, March 2006 vol. 117 no. 3; 673-680.

Study Design:

Randomized controlled trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effect of decreasing the SSB consumption on body weight.

Inclusion Criteria:

- Consuming at least one serving (i.e., 360ml or 12 fluid ounces) per day of SSB (i.e., soft drinks, juice drinks containing less 100% juice, punches, lemonades, iced teas and sports drinks).
- Lived predominantly in one household (no more than one weekend every two weeks in a secondary household).

Exclusion Criteria:

- Currently dieting for the purpose of weight loss
- Taking medications that might affect body weight
- Reported smoking at least one cigarette in the past week or were diagnosed as having a major medical illness or eating disorder
- BMI below the 25th percentile.

Description of Study Protocol:**Recruitment**

- Conducted in collaboration with a local high school that provided mailing lists and space for obtaining measurements. Packets containing an invitation letter and informed consent and assent documents were sent to the parents of all students enrolled at the school. Parents were instructed to contact staff members by telephone, if interested in obtaining more information about the protocol. Approved by the institutional review board at Children's Hospital Boston.

Design

- Randomized.

Intervention

- Intervention group received weekly home deliveries of non-caloric beverages for 25 weeks. The target number of individual beverage servings (i.e., 360ml or two fluid ounces per referent serving) delivered to each home was based on household size. Four servings per day for the subject and two servings per day for each additional member of the household.
- Distributed order forms to each household for selecting beverage preferences from a variety of options (bottled water and diet beverages). The target number of delivered servings was about five units per week for the subject and three units for each additional member of the household. The units contain bundles of four to six cans or bottles with volumes ranging from 300ml to 720ml (10-24 fluid ounces).
- Written instructions regarding beverage consumption were mailed to subjects at the beginning of the intervention period. They were also contacted by telephone during the first week of the intervention to speak with the subject and a parent. Telephone contact provided an opportunity to reinforce instructions, answer questions and address concerns. Contacts were made by telephone on a monthly basis throughout the intervention to assess satisfaction with beverage choices and deliveries, discuss beverage consumption and provide motivational counseling.
- Monthly basis magnets with "Think Before You Drink" printed on them were sent to provide data-based information with regard to excess energy intake, weight gain, tooth decay and hunger.
- Subjects in the control group were asked to continue their usual beverage consumption habits throughout the 25-week intervention period. They received weekly home deliveries of non-caloric beverages for four weeks after completion of follow-up measurements as a benefit for participating in the study.

Blinding Used

- Personnel were masked to sequence.

Statistical Analysis

- Provided 80% power to detect an effect size of 0.51 (mean change divided by SD of change), using a 5% Type I error rate.
- Comparisons of baseline demographic, anthropometric and behavioral characteristics

between the intervention and the control groups were done by student's T-test for continuous measures and Fischer's Exact Test for discrete variables.

- Multiple linear regressions and SAS were also used.

Data Collection Summary:

Timing of Measurements

- *Primary endpoint*: The change in BMI from baseline to follow-up.
- Weight and height were measured using an electronic scale.
 - Subjects removed shoes and heavy outerwear.
 - Measured in duplicates.
 - BMI was calculated as total (kilograms) divided by height (meters) squared.
- *Dietary and physical activity recall*: Two 24-hour dietary and physical activity recall interviews were conducted over the telephone at baseline and another two at the end of the intervention period. Telephone calls were unannounced so that the subject did not know the exact dates of the interviews in advance.
- Dietary intake was assessed by a multiple-pass method using the Nutrition Data System for Research software.
- Immediately after the dietary recall portion, the subject was asked to recall physical activity and inactivity including sleep.
- Before the first telephone interview, in person group training sessions were held focusing on how to estimate food and beverage portion sizes and how to describe the intensity of the physical activity.

Description of Actual Data Sample:

- *Initial N*: 103 adolescents (47 males and 56 females)
- *Age*: 13 to 18 years.

Baseline Characteristics of Subjects in the Intervention and Control Group

Characteristic	N (%) or Mean±SD	N (%) or Mean±SD	pa
	Intervention	Control	
Number of subjects	53 (100)	50 (100)	
Gender			
Male	24 (45)	23 (46)	1.0 ^b
Female	29 (55)	27 (54)	
Race			
White	18 (34)	19 (38)	0.69
Non-white	35 (66)	31 (62)	

Ethnicity			
Hispanic	11 (21)	7 (14)	0.44
Non-hispanic	42 (79)	43 (86)	
Age (Years)	16.0±1.1	15.8±1.1	
Weight (kg)	72.1±20.5	69.6±19.2	0.37
Height (cm)	167±9	167±9	0.53
BMI (kg/m ²)	25.7±6.3	24.9±5.7	0.88
Weight Status			
BMI<85th percentile	28 (53)	29 (58)	0.69 ^b
BMI≥85th percentile	25(47)	21 (42)	
Household Income ^c			
<\$30,000	19(38)	20 (41)	0.97
\$30,000 to \$59,999	16(32)	14 (29)	
≥\$60,000	15(30)	15 (31)	
Residing in Subsidized Housing	10(19)	7 (14)	0.60
Household Size (Family Members)	3.1±1.1	3.2±1.1	0.96

A: Comparison by Student's T-test or Fischer's Exact Test

B: Balanced by stratified randomization

C: Three non-respondents in the intervention and in the control group.

Summary of Results:

Baseline Measures

- There were no significant group differences between the intervention and control subjects in demographics (gender, race, ethnicity, age, household income and household size) or anthropometrics (weight, height and BMI). Groups did not differ in baseline levels for energy intake (sugar-sweetened beverages), non-caloric beverage intake, physical activity television rating or total media time.

Process Measures

- Completed all six telephone contacts: 83% in the intervention group (44 of 53 subjects) for an average of 5.8±0.6 (mean±SD) counseling calls per subject.
- Energy intake from sugar-sweetened beverages decreased by 82% for the intervention group ($P<0.0001$) and did not change for the control group.
- There were no changes for either group for physical activity, television viewing or total media time.

Outcome

- Change in BMI adjusted for gender and age was $0.07 \pm 0.14 \text{ kg/m}^2$ (mean \pm SE) for the intervention group and $0.21 \pm 0.15 \text{ kg/m}^2$ for the control group. The net difference, $-0.14 \pm 0.21 \text{ kg/m}^2$, was not significant overall but varied considerably over the range of baseline BMI.
- Baseline BMI was a significant modifier. Subjects in the upper baseline BMI tertile, BMI changed significantly between the intervention ($-0.63 \pm 0.23 \text{ kg/m}^2$) and control ($+0.12 \pm 0.26 \text{ kg/m}^2$) groups, a net effect of $-0.75 \pm 0.34 \text{ kg/m}^2$.
- No significant effects were seen for subjects in the middle and lower tertiles.

Daily Energy Intake From Sugar-Sweetened Beverages, Physical Activity, Television Watching and Total Media Time in the Intervention and Control Groups

	Mean \pm SD	Mean \pm SD	pa
Variable	Intervention	Control	
Number of Subjects	53	50	
EI (SSB, kJ ^b)			
Baseline	1,466 \pm 781	1,596 \pm 1,109	0.50
Change	-1,201 \pm 836 ^c	-185 \pm 945	0.0001
Non-Caloric Beverage Intake (ml)			
Baseline	254 \pm 304	170 \pm 245	0.12
Change	396 \pm 493 ^c	78 \pm 523	0.002
Physical Activity (MET Level)			
Baseline	1.74 \pm 0.35	1.63 \pm 0.23	0.08
Change	-0.12 \pm 0.37	-0.03 \pm 0.32	0.18
Television Viewing (Hours)			
Baseline	2.17 \pm 1.36	2.62 \pm 1.75	0.14
Change	0.05 \pm 1.56	-0.19 \pm 1.85	0.47
Total Media Time (Hours ^d)			
Baseline	4.57 \pm 2.42	5.28 \pm 3.38	0.22
Change	-0.50 \pm 2.56	-0.31 \pm 3.33	0.75

A: Student's T-test

B: To convert kilojoules to kilocalories, divide by 4.2

C: Significant change from baseline, $P < 0.0001$

D: Sum of time spent watching television, using a computer (other than homework) and playing video games.

Author Conclusion:

- The beneficial effect on body weight of reducing SSB consumption increased with increasing baseline body weight, offering additional support for the American Academy of Pediatrics guidelines to limit SSB consumption.
- Decreasing the consumption of SSBs seems to be a promising strategy for the prevention and treatment of overweight in adolescents. Large-scale trials are needed to evaluate the effects of this strategy over the long term, focusing on the heaviest adolescents.

Strengths

- A novel intervention
- A demographically diverse sample
- 100% completion rate among randomly assigned subjects
- The diversity and high retention rate of the study cohort enhance the generalizability of the results.

Limitations

- Relatively small sample size and short intervention period
- Reliance on self-reporting and process evaluation
- Did not stage pubertal status.

Reviewer Comments:

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

	7.6.	Were other factors accounted for (measured) that could affect outcomes?	N/A
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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